UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: June 21, 2001

SUBJECT: **Thiabendazole** (060101) and **Thiabendazole salt** (060102): A Revised HED Risk Assessment for the Reregistration Eligibility Decision (RED) Document. Case No. 2670. Barcode D275829

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And

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Attached is HED's revised risk assessment of the fungicide, thiabendazole for purposes of issuing a Reregistration Eligibility Decision (RED) Document for this active ingredient. Error corrections and comments from Novartis dated June 19, 2000 have been incorporated. The disciplinary science chapters and other supporting documents have also been revised where necessary and are available as attachments to this document. This chapter incorporates information from the toxicology assessment by David Nixon, the assessments from human incidence data by Jerry Blondell and Monica Spann, the residue chemistry assessment and dietary exposure and risk estimates by Thurston Morton, and the occupational and residential exposure assessment by Dave Jaquith.

HUMAN HEALTH RISK ASSESSMENT

Thiabendazole (TBZ)

U. S. Environmental Protection Agency
Office of Pesticide Programs
Health Effects Division (7509C)

Suhair Shallal, Risk Assessor
June 21, 2001

HUMAN HEALTH RISK ASSESSMENT

Thiabendazole (TBZ)

Phase 3– Public Comment Phase

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1.0 EXECUTIVE SUMMARY

1.1 Use and Formulation

Thiabendazole [2-(4-thiazolyl)benzimidazole] is a systemic benzimidazole fungicide used to control fruit and vegetable diseases such as mold, rot, blight and stain. It is also active against storage diseases and Dutch elm disease. Thiabendazole is used medicinally as a chelating agent to bind metals; in addition, it is administered to treat several helminth species such as roundworms in livestock and humans. These uses are regulated by FDA and have not been included in this risk assessment.

At this time, products containing thiabendazole are mainly intended for commercial and on-farm use. The only products containing thiabendazole intended for residential use include preservatives and antimicrobials incorporated in paints, adhesives, paper and carpet. The low concentrations of thiabendazole in these products greatly reduces the potential for significant exposure.

Thiabendazole is registered for use on bananas, carrots, citrus fruits, mushrooms, pome fruits, potatoes, soybeans, tobacco, and wheat. The registrant wishes to support tolerances with no US registrations for papaya, mango, cantaloupe, avocado, and strawberry. Thiabendazole was previously manufactured by Merck & Co., Inc. under the trade name Mertect. The technical active ingredient and all of Merck's end-use products were transferred (8/97) to Sygenta Crop Protection, Inc., who is now the basic producer. Thiabendazole formulations registered to Syngenta for use on food/feed crops and tobacco include two flowable concentrate (FlC) formulations, a water dispersable granular (dry flowable, DF) formulation, and a ready-to-use (RTU) formulation. These products may be applied as a pre-planting application (potato seed-pieces, soybean seed treatment or wheat seed treatment), chemigation (mushroom), foliar (cantaloupe, strawberry), or post-harvest applications.

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS 860.1000). As a result of changes to Table 1, additional thiabendazole residue data are now required for some commodities; these data requirements have been incorporated into this document. These new data requirements will be imposed at the issuance of the Thiabendazole RED but should not impinge on the reregistration eligibility decisions for thiabendazole.

1.2 Risk Assessment and Characterization

HED evaluated the toxicological, residue chemistry, and exposure databases for thiabendazole and determined that the data are adequate to support a reregistration eligibility decision. The need for revisions to dietary exposure/risk assessments will be determined upon receipt of the required residue chemistry data. In assessing aggregate risk, HED considered potential dietary exposure of the general population to thiabendazole residues from food and drinking water, and potential dermal and inhalation exposure from residential uses. HED also considered dermal and inhalation exposure to occupational handlers and workers during post-harvesting activities.

1.3 Hazard Identification and Dose response

The toxicological database is complete and indicates that thiabendazole has **low to moderate acute toxicity via the dermal and oral routes and is not a sensitizer**. In the rat, death and clinical signs of toxicity were observed at high dosages. In subchronic and chronic studies, the thyroid and liver are the primary target organs of thiabendazole. Thiabendazole produced a marginally statistically significant increase in thyroid adenomas in a rat carcinogenicity study. Thiabendazole also produced a treatment-related increase in absolute and relative liver weights in both sexes in a chronic dog study.

The toxicity endpoints used in this document to assess hazard include acute dietary and chronic dietary reference doses (RfDs), and short-, intermediate-, and long-term dermal and inhalation no observable adverse affect levels (NOAELs). Decreased body weight in a developmental toxicity study was the toxicity endpoint used for acute dietary and short-term occupational exposure. Decreased body weight gain and liver hypertrophy in a chronic toxicity study were used as the toxic endpoints for chronic dietary, while decreased body weight gain and histopathologic changes in liver and thyroid in a 14-week oral toxicity study were the toxicity endpoint used for intermediate-term occupational exposure assessment. The uncertainty factors were 100 for all exposure types.

The data submitted to the Agency as well as those from the published literature, with one exception, demonstrate no increased sensitivity of rats, mice, or rabbits to *in utero* or early postnatal exposure to thiabendazole. The exception in the published literature reports cleft palate formation in mouse fetuses following thiabendazole administration to mothers (Ogata et al., 1984). The developmental effects in fetuses or neonates occurred at or above doses that caused maternal or parental toxicity; therefore, HED's FQPA Safety Factor Committee

recommended that the **10X FQPA safety factor be removed.** The Committee concluded that the safety factor could be removed for thiabendazole because:

i. The toxicology database is complete for FQPA assessment;
ii. The toxicity data provide no indication of increased susceptibility of young rats or rabbits to thiabendazole;
iii. The HIARC determined that a developmental neurotoxicity study is not required;
iv. The exposure assessments will not underestimate the potential dietary (food and drinking water) exposures for infants and children from the use of thiabendazole.

The Health Effects Division (HED) Cancer Assessment Review Committee (CARC) met on May 26, 1999 and concluded that thiabendazole is "**likely to be carcinogenic to humans**." For human cancer risk assessment, the MOE approach was recommended by CARC during their meeting. The use of the MOE approach is supported by the weight-of-evidence that suggests that thiabendazole may interfere with thyroid-pituitary homeostasis and does not act via a mutagenic mode of action. Children are not expected to be more susceptible to thiabendazole-induced thyroid effects than adults.

1.4 Dietary Exposure and Risk

HED conducted acute and chronic dietary (food) exposure analyses using the Dietary Exposure Evaluation Model (DEEM™). In both assessments, dietary exposure (consumption) was compared to a population adjusted dose (PAD). The PAD is equal to the acute or chronic RfD divided by the FQPA factor; in the case of thiabendazole, the FQPA factor has been removed and therefore the PAD is equal to the RfD. HED considers dietary residue contributions greater than 100% of the PAD to be of concern.

Estimated acute dietary exposure is above HED's level of concern for children 1-6 yrs. Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) in the assessment resulted in estimated dietary exposures (99.9^{th} percentile) corresponding to 57 % aPAD for the general US population and 117 % aPAD for children 1-6 years old, the most highly exposed population subgroup.

Estimated chronic dietary exposure is below HED's level of concern. Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) results in a maximum risk of 2 % of the chronic PAD (% cPAD) for children 1-6. Dietary risk for the general US population was estimated to be 1 % cPAD.

Using the margin of exposure (MOE) approach, estimated cancer dietary exposure is below HED's level of concern. Use of a combination of PDP monitoring data, field trial data, tolerance level residues, and calculated livestock anticipated residues (ARs) results in an MOE

of 9,750 for the general US population.

1.5 Environmental Fate and Drinking Water Analysis

The Environmental Fate and Effects Division (EFED) has concluded that based on the available data, thiabendazole is extremely persistent in the environment. The extrapolated half-lives ranged from 833-1100 days in cropped plots and from 1093-1444 days in bare-ground plots. Thiabendazole photodegrades in water, but is quite stable to photolysis in soil and to hydrolysis. It does not metabolize significantly in soils, under aerobic and anaerobic conditions. Although it is shown to be quite persistent in the environment, EFED (draft memo by Thuy Nguyen, D245780) believes that thiabendazole will strongly bind to soil, thus limiting the amount available for leaching into groundwater and for runoff into surface water. No data were available for the degradates of thiabendazole; however, since they comprised a relatively small fraction (less than 10%) of the total applied radioactivity in the laboratory studies, EFED believes that their concentrations in the fields will not be appreciable. The parent compound was, therefore, the only metabolite considered in the water assessment.

Thiabendazole use on mushrooms is not expected to cause any drinking water contamination, since treatment is performed indoors, and leaching into groundwater and runoff to surface water are unlikely to occur. Treatment of wheat seeds is also indoor, but drinking water concern may arise since the treated seeds are later planted in the field. The following assessment pertains only to the use of treated seeds planted in the fields.

The surface water GENEEC acute (peak) and chronic (56 day) values are in the proximity of 2 ppb. These values represent the upper-bound estimates of the concentrations that might be found in surface water due to the use of thiabendazole, and therefore can be used in screening calculations. For groundwater, SCI-GROW reports 0.01 ppb for thiabendazole residues, based on the maximum application rate. This is expected as thiabendazole does not seem to significantly leach into groundwater, due to its high soil/water partitioning coefficients. Terrestrial field study results also confirm the low leaching potential of this chemical in the fields, as thiabendazole was not detected in any of the soil samples below the 12" layer.

The EECs for surface water (GENEEC) as well as for groundwater (SCI-GROW) were less than the acute DWLOCs, except for children 1-6, indicating that acute aggregate exposure to thiabendazole in food and water is below HEDs level of concern. Similarly, chronic DWLOCs were less than the estimated chronic values for ground and surface water indicating that the chronic aggregate exposure to thiabendazole in food and water is below HEDs level of concern.

1.6 Occupational Exposure and Risk

No chemical-specific handler studies are available. Baseline dermal and inhalation exposure assessments using PHED Version 1.1 surrogate data are presented in the Occupational and

Residential Exposure RED Chapter (D. Jaquith, 9/00, D267084). To address scenarios not covered by PHED, it was necessary to use data from studies found in the scientific literature. The estimated exposures from dermal and inhalation routes were combined to yield a total exposure that was used for risk assessment.

Occupational risk estimates exceed HED's level of concern. Several of the occupational handler scenarios reflecting use of baseline protective clothing exceed HED's level of concern defined by target MOEs of 100 for short- and intermediate-term dermal risk, and 100 for short- and intermediate-term inhalation risk. MOEs for occupational exposure risk at baseline ranged from 32-77, for manual seed treatment, post-harvest activities described above and application to mushroom scenarios as described in Table 9. Short- and intermediate-term dermal risks for these scenarios are mitigated with PPE (personal protective equipment) and/or engineering controls such that MOEs are > 100 and below HED's level of concern, except manual seed treatment. Manual seed treatment is expected to be used less often than commercial seed treatment No suitable chemical specific data is available for estimating occupational exposure due to commercial seed treatment; however, a surrogate study indicates that exposures from large scale seed treatment with commercial equipment is relatively low (D. Jaquith, 9/00, D267084). The study was published in 1983. It is the Agency's understanding that current technology is such that the treatment system is closed and treatment systems are not manually operated; therefore, exposures from a factory setting would not be expected to exceed that from manual seed treatment. Additionally, Thiabendazole hypophosphite is used for treatment of elm and sycamore diseases by injection into the roots. This activity is not expected to lead to exposures greater than those for other handler uses for thiabendazole and is expected to be negligible (D. Jaquith, 9/00, D267084).

The exposure estimate for workers involved in post-harvest activities, ie., sorting/packing, derived in lieu of data should be considered to be very conservative for the following reasons: (1) it was assumed that all of the thiabendazole on the treated surface could be transferred to the skin. The chemical is usually part of a wax matrix and quantitative transfer to the skin is unlikely; and (2) the transfer coefficients for the hands were obtained from a field study in which contact with contaminated foliage was highly probable; a conveyor belt treatment line would be unlikely to have such a high degree of contact (probably restricted to fingertips only). Further mitigation might be achieved by reduction in the amount handled.

Residential risk estimates are not expected to exceed occupational post-application exposure and therefore do not exceed HED's level of concern. Non-occupational exposure may include application of thiabendazole-treated paints and exposure to thiabendazole-treated carpets.

1.7 Aggregate exposure and Risk

HED finds that aggregate short-, intermediate-term and chronic dietary (food and water) risk estimates , in addition to non-occupational exposure estimates, associated with the

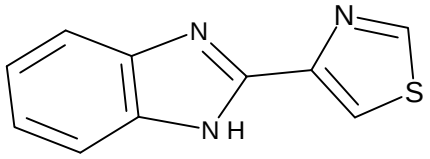
consumption of residues of thiabendazole do not exceed HED's level of concern, except for children 1-6, for which food alone exceeds the level of concern.

1.8 Conclusion

Acute dietary (food and water) exposure do exceed HED's level of concern for children 1-6 years and appropriate mitigation measures to reduce the potential for oral exposure to thiabendazole are recommended.

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION

Thiabendazole is a preventative and eradicant chemical against molds, rots and blight on fruits and vegetables. It is used orally for roundworm control in humans and livestock.



MOLECULAR FORMULA:	C_{10} H_7 N_3 S
MOLECULAR WEIGHT:	201.26 g/mole
PC Code:	060101
CAS Registry No.:	148-79-8

Thiabendazole technical is a colorless crystalline solid with a melting point of 304-305 °C, octanol/water partition coefficient (K_{ow}) of 240-285 at pH 7, and vapor pressure of 4 x 10^{-9} mm Hg at 25 °C. Thiabendazole is soluble in water at 0.028-0.030 mg/mL at 25 °C, and is soluble in organic solvents at 0.004 mg/mL in hexane, 0.195 mg/mL in toluene, 2.13 mg/mL in ethyl acetate, 2.36 mg/mL in chloroform, 2.90 mg/mL in acetone, and 8.72 mg/mL in methanol at 25 °C.

3.0 HAZARD CHARACTERIZATION

Thiabendazole has moderate acute oral toxicity (Category III) to rats [LD_{50} = 4735 mg/kg/day (♂ and ♀), and moderate dermal toxicity (Category III) [LD_{50} = >2000 mg/kg/day] (♂ and ♀) . The acute inhalation study was waived for thiabendazole hypophosphite salt (20% a.i.) because it has little opportunity for vaporization or aerosolization since it is used for direct injection into root flares. Therefore, there is a negligible risk of inhalation exposure

to vapor or aerosol during use. Thiabendazole base is also known to have a very low vapor pressure and is not expected to contribute greatly to exposures via the inhalation route. In primary eye and primary skin irritation studies, thiabendazole was found to be non-irritating. Thiabendazole is not a dermal sensitizer.

In the rat, death and clinical signs of toxicity were observed at high dosages. Death was reported at dosages $\geq$ 2222 mg/kg after a single dosage (Acute Oral Study, MRID 41258201) in males and females. There was an increased incidence of clinical signs with increasing dosage and duration. No effects were observed in the structural neuropathological (gross and histopathology) measurements.

The thyroid and liver are the primary target organs of thiabendazole. In the rat dietary subchronic study (MRID 42942802), there were increases in liver and thyroid absolute weights at $\geq$160 mg/kg/day in females. Relative liver weights were increased at $\geq$ 40 mg/kg/day in females and $\geq$160 mg/kg/day in males. Absolute thyroid weights were increased in females at $\geq$160 mg/kg/day and relative thyroid weights in males and females at $\geq$160 mg/kg/day. Histologically, hepatic centrilobular hypertrophy and thyroid follicular cell hypertrophy of males and females were observed at $\geq$40 mg/kg/day.

In the rat gavage subchronic study (MRID 42942801), there was hepatic centrilobular hypertrophy in males and females at $\geq$100 mg/kg/day, increased absolute liver weight in females $\geq$100 mg/kg/day and in males at 400 mg/kg/day. Relative liver weight was increased in males and females at $\geq$100 mg/kg/day. There was follicular cell hyperplasia in males and females at $\geq$100 mg/kg/day. Relative thyroid weight was increased in males and females at $\geq$100 mg/kg/day. Absolute thyroid weight was increased at 400 mg/kg/day. There were variations in sacrifice times of different groups and variable dosages of thiabendazole were used; therefore this study was unacceptable.

In the chronic dog study, thiabendazole produced a treatment-related increase in absolute and relative liver weights in both sexes. The absolute and relative thyroid weights were increased in animals at the highest dose tested (HDT). On histopathology there was bile duct vacuolization in the MDT and HDT males and females. There was thyroid follicular enlargement in males and females at HDT. There were increases in splenic erythropoiesis and hemosiderosis in the MDT and HDT males and females.

Thiabendazole has been shown to induce thyroid tumors in male and female rats. The Health Effects Division (HED) Cancer Assessment Review Committee (CARC) met on May 26, 1999, and concluded that thiabendazole is "**likely to be carcinogenic to humans**." A mode of action was established in which these tumors were attributed to interference with thyroid-pituitary homeostasis. For purposes of this risk assessment, the MOE approach will therefore be used to estimate cancer risk. Thiabendazole also causes increased liver weight and hepatocellular hypertrophy presumably via induction of microsomal enzymes. Thiabendazole is not a mutagen. The lack of mutagenicity corroborates the notion that the thyroid tumors are induced by a non-mutagenic mechanism. It is also recommended that thiabendazole undergo further testing to ascertain its potential to modulate hormone levels and other endocrine

mediators.

3.1 Acute Toxicity

Results of acute toxicity studies, primary eye and dermal irritation studies and a dermal sensitization study with thiabendazole technical material are summarized in Table 1. Thiabendazole is moderately toxic (Toxicity Category III) via the oral and dermal routes. In a primary eye and dermal irritation study in rabbits, the technical was found to be non-irritating (Toxicity Category IV). Thiabendazole is also non-sensitizing (Toxicity Category IV).

Table 1- Acute Toxicity of Thiabendazole

Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
81-1	Acute Oral	41258201	LD_{50} = 4735 mg/kg	III
81-2	Acute Dermal	41258202	LD_{50} = >2000 mg/kg	III
81-3	Acute Inhalation	Waived	HED Doc. No. 010140	
81-4	Primary Eye Irritation	40789806	Non-irritating	IV
81-5	Primary Skin Irritation	40789807	Non-irritating	IV
81-6	Dermal Sensitization	40271701	Non-sensitizer	IV
81-8	Acute Neurotoxicity	Waived	HED Doc. No. 006934	

3.2 Endpoint Selection

On June 1 and 17, 1999 the Health Effects Division (HED) Hazard Identification Assessment Review Committee evaluated the toxicology data base of thiabendazole, established acute and chronic reference doses (RfD's) for dietary exposure and selected the toxicological endpoints for occupational exposure and residential risk assessments. The dosages and toxicological endpoints selected for various exposure scenarios are summarized below. The absorbed fraction of each exposure was calculated in order to convert dermal and inhalation exposures to an equivalent oral dose using a dermal absorption rate of 60% and inhalation absorption factor of 100% .

Table 2. Summary of Endpoints

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary (females 13+)	NOAEL= 10 mg/kg/day LOAEL = 40 mg/kg/day UF = 100 FQPA SF = 1X	Decreased fetal body weight (females 13+)	Developmental Study–Rat
Acute Dietary (general population)	NOAEL= 10 mg/kg/day LOAEL = 40 mg/kg/day UF = 100 FQPA SF = 1X	Decreased maternal body weight seen during gestation (general pop.)	Developmental Study–Rat
Acute RfD (General Population) = 0.1 mg/kg/day Acute RfD (Females 13+) = 0.1 mg/kg/day mg/kg/day		aPAD (Gen. Pop.)= RfD/FQPA SF= 0.1 mg/kg/day aPAD (Females 13+)= RfD/FQPA SF= 0.1	
Chronic Dietary	NOAEL= 10 mg/kg/day LOAEL = 30 mg/kg/day UF = 100 FQPA SF = 1X	Based on decreased body weight gains and liver hypertrophy	2-Year Feed/chronic carcinogenicity
Chronic RfD = 0.1mg/kg/day Cancer POD = 10 mg/kg/day		cPAD = RfD/FQPA SF = 0.1 mg/kg/day	
Short-Term (Dermal and Inhalation)	NOAEL=10 mg/kg/day LOAEL = 40 mg/kg/day	Based on decreased fetal body weights	Oral Developmental Toxicity–Rat
Intermediate-term (Dermal and Inhalation)	NOAEL= 10 mg/kg/day LOAEL = 40 mg/kg/day	Based on reduced body weight gains and histopathological changes in the bone marrow, liver, and thyroid	Fourteen Week Oral Toxicity (Feeding) Study

Long-Term (Dermal and Inhalation)	NOAEL= 10 mg/kg/day LOAEL = 30 mg/kg/day	Based on decreased body weight gains and liver hypertrophy	2-Yr feed/chronic Carcinogenicity
Dermal Absorption factor = 60%		Inhalation Absorption Factor = 100%	

3.3 FQPA Considerations

The FQPA Safety Factor Committee met on August 30, 1999 to evaluate the hazard and exposure data for thiabendazole and recommended that the FQPA Safety Factor be **removed** (1X) in assessing the risk posed by this chemical.

The Committee concluded that the safety factor could be removed for thiabendazole because:

i. The toxicology database is complete for FQPA assessment;
ii. The toxicity data provide no indication of increased susceptibility of young rats or rabbits to thiabendazole;
iii. The HIARC determined that a developmental neurotoxicity study is not required;
iv. The exposure assessments will not underestimate the potential dietary (food and drinking water) exposures for infants and children from the use of thiabendazole.

3.4 Endocrine Disrupter Effects

The Food Quality Protection Act requires that EPA develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." EPA has been working with interested stakeholders, including other government agencies, public interest groups, and industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disrupter Screening Program was published in the Federal Register of December 28, 1998 (63 FR 71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of thiabendazole and its end-use products for endocrine effects may be required.

4.0 EXPOSURE ASSESSMENT

4.1 Summary of Registered Uses

Thiabendazole [2-(4-thiazolyl)benzimidazole] is a fungicide registered for use on bananas, carrots, citrus fruits, mushrooms, pome fruits, potatoes, soybeans, tobacco, and wheat. The registrant wishes to support tolerances with no US registrations for papaya, mango, cantaloupe, avocado, and strawberry. Thiabendazole was previously manufactured by Merck & Co., Inc. under the trade name Mertect. The technical active ingredient and all of Merck's end-use products were transferred (8/97) to Novartis Crop Protection, Inc., who is now the basic producer. Thiabendazole formulations registered to Novartis for use on food/feed crops and tobacco include two flowable concentrate (FlC) formulations, a water dispersable granular (dry flowable, DF) formulation, and a ready-to-use (RTU) formulation. These products may be applied as a pre-planting application (potato seed-pieces, soybean seed treatment or wheat seed treatment), chemigation (mushroom), foliar (cantaloupe, strawberry), or post-harvest applications.

Thiabendazole base (060101), a fungicide, is formulated as a RTU (0.1 to 50% ai), Flowable Concentrate (0.35 to 98.5% ai), Dust (0.5 to 98.5% ai), Emulsifiable Concentrate (0.1 to 98.5% ai), Wettable Powder (98.5% ai), Granular (89% ai), and Water Dispersable Granules (42.28% ai - SLN only). Based on REFs, thiabendazole base has post-harvest uses on orchard crops (citrus, pome fruits, tropical fruits), potatoes, carrots, beans, and sugar beets. It is also used in mushroom houses, as a seed treatment (soybeans and wheat), tobacco preservative, in-can paint preservative, and preservative of applied films.

Thiabendazole hypophosphorous salt (060102) is formulated as a 26.6% ai soluble concentrate and a 20% ai RTU. Based on REFs, uses include ornamental elm and sycamore trees and as a preservative in adhesives, coatings, paper, textiles, and paints.

A search of the Reference Files System (REFS) conducted 7/7/00 identified two thiabendazole manufacturing-use products (MP) registered under PC Code 060101: the Novartis Crop Protection, Inc. 98.5% T (EPA Reg. Nos. 100-917 and 100-963). No MPs are registered under PC Code 060102 (hypophosphite salt). The Novartis product (EPA Reg. No. 100-917) was registered 8/98; the CSF dated 11/21/97 obtained from the product jacket indicates that the product is repackaged from a technical product which was canceled 7/21/98. Novartis must identify the current source product. Only the registered Novartis 98.5% T/TGAIs are subject to a reregistration eligibility decision.

A more recent search of the Agency's Reference Files System (REFS) on 7/7/00 indicated that there are three thiabendazole end-use products (EPs) with uses on food/feed crops and tobacco registered to Novartis Crop Protection, Inc. End-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) should be amended such that they are consistent with the basic producer's labels. These amendments have been summarized in HED's Product and Residue Chemistry Chapter (T. Morton, D267871). The EPs include the following:

Thiabendazole End-Use Products with Food/Feed and Tobacco Uses Registered to Novartis

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
100-887 [a]	5/98	40% RTU	Mertect® 40 Antimycotic
100-889	10/93	3.8 lb/gal FlC	Mertect® 340-F Fungicide
100-890	10/93	2.7 lb/gal FlC	Mertect® LSP Fungicide

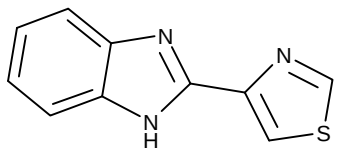
[a]This product is registered only for post-harvest use on tobacco.

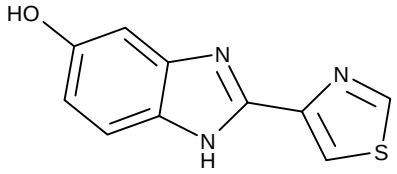
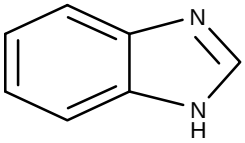
4.2 Dietary Exposure

DEEM® residue inputs for commodities (avocado, mango, papaya, and strawberry) from outside the United States used field trial residue values from specific use patterns. It is not known whether these reflect the use rate which would result in the highest residues. Tolerances for residues of thiabendazole in/on plant raw agricultural commodities (RACs) and processed plant commodities have been established under 40 CFR§180.242(a). Tolerances have also been established for the combined residues of thiabendazole and its metabolite, 5-hydroxythiabendazole, in milk at 0.4 ppm and in eggs, meat, meat-by-products (mbyp), and fat at 0.1 ppm [40 CFR§180.242(b)].

The qualitative nature of the residue in plants is adequately understood based on soybean, sugar beet, and wheat metabolism studies. The residues of concern in plants include thiabendazole and benzimidazole, free and conjugated (L. Cheung, 3/11/92). The HED Metabolism Assessment Committee (MARC; T.Morton, 12/2/99, D261103) concurred that thiabendazole residues of concern in plants include thiabendazole and its metabolite benzimidazole (free and conjugated). The qualitative nature of thiabendazole residues in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies. The HED Metabolism Committee (L. Cheng, 2/14/92) concluded that the thiabendazole residues to be regulated in animal commodities will include thiabendazole, 5-hydroxythiabendazole (free and conjugated), and benzimidazole (See Figure 1).

Figure 1. Chemical name and structure of thiabendazole and its residues of concern in plant and animal commodities.

Common Name/Chemical Name	Chemical Structure
Thiabendazole 2-(4-thiazolyl)benzimidazole	

Common Name/Chemical Name	Chemical Structure
5-Hydroxy-thiabendazole (free and conjugated) 2-(4-thiazolyl)-5-hydroxybenzimidazole	
Benzimidazole (free and conjugated)	

4.2.1 Dietary Exposure (food source)

HED conducts dietary risk assessments using the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. For acute dietary risk assessments, the entire distribution of single-day food consumption events is combined with either a single residue level (deterministic analysis, risk at 95th percentile of exposure reported) or a distribution of residues (probabilistic analysis, referred to as "Monte Carlo," risk at 99.9th percentile of exposure reported) to obtain a distribution of exposure in mg/kg/day. For chronic dietary risk assessments, the three-day average of consumption for each population subgroups is combined with average residues in commodities to determine average exposure in mg/kg/day.

Anticipated residues (ARs) for acute and chronic dietary exposure analyses (T. Morton, 9/22/99, D259731), were generated in conjunction with the HED Chemistry RED (T. Morton, 12/8/99, D251079) and presented to the HED ChemSAC (9/22/99). These anticipated residues have been revised (T. Morton, 9/7/00, D267542). Numerous State and Local Needs products (SLNs) are registered for peas, beans, dry beans, and chickpeas, therefore, all of Crop Group 6 (Legume Vegetables-Succulent and Dried) was included in the revised dietary exposure analysis. Some of these SLNs include a statement on the label restricting the seed peas or beans for export only but HED does not consider this restriction practical. Diversion of the seed peas or seed beans to the US market is possible. The Biological and Economic Analysis Division (OPP/BEAD) has provided usage information for thiabendazole (email from I. Yusuf, 9/13/99).

Fruit and vegetable PDP data (1995-1997) reflected analysis for parent thiabendazole only. Given that post-harvest applications result in the highest potential thiabendazole residues in/on raw agricultural commodities, HED concluded that residues of benzimidazole (free and conjugated) are unlikely to contribute significantly to the total thiabendazole residues (S. Mason, D207850/D214188, 1/99). Therefore, PDP data for all commodities except wheat, legume vegetables (succulent and dried), cantaloupe, strawberry and sweet potato could be

used directly. A factor of 1.8 to convert the PDP data to account for benzimidazole residues in wheat grain was calculated from the nature of the residue study in wheat (L. Cheng, D165718, 3/11/92). A factor of 1.5 to convert the PDP data was calculated from the nature of the residue study in soybean (L. Cheng, D165718, 3/11/92) and used for legume vegetables (succulent and dried). A factor of 1.4 to convert the PDP data to account for benzimidazole residues in sweet potato tuber was calculated from the nature of the residue study in sugar beet (L. Cheng, D165718, 3/11/92). The highest factor from the metabolism studies of 1.8 was used to convert the PDP and field trial data to account for benzimidazole residues in cantaloupe and strawberry. Milk PDP data included analyses for thiabendazole and 5-hydroxythiabendazole. Residues of benzimidazole were not detected in milk in the metabolism study (L. Cheng, D170818, 3/2/92). Therefore, PDP data were used for acute and chronic dietary exposure analyses. For all analyses the ½ Limit of Detection (LOD) value was a weighted average of all laboratory limits of detection. Several commodities which had PDP monitoring data contained overtolerance residues. In addition, when decompositing the PDP data for several commodities overtolerance values were generated. A comparison of the dietary risk estimates was conducted by lowering these overtolerance residue values to the tolerance for the given commodity. The acute dietary risk estimates for most population subgroups were not greatly affected, including the children (1-6 years) subpopulation which remained above HED's level of concern.

4.2.1.1 Acute Dietary Exposure Assessment

Estimated acute dietary exposure is above HED's level of concern for children 1-6 yrs. Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) in the assessment resulted in estimated dietary exposures (99.9th percentile) corresponding to 57 % aPAD for the general US population and 117 % aPAD for children 1-6 years old, the most highly exposed population subgroup (Table 3).

4.2.1.2 Chronic Dietary Exposure Assessment

Estimated chronic dietary exposure is below HED's level of concern. Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) results in a maximum risk estimate of 2 % of the chronic PAD (% cPAD) for children 1-6. Dietary risk estimate for the general US population was estimated to be 1 % cPAD (Table 3).

4.2.1.3 Cancer Dietary Exposure Assessment

Thiabendazole induced thyroid tumors in male rats. Thiabendazole also causes increased liver weight and hepatocellular hypertrophy presumably via induction of microsomal enzymes. Thiabendazole is not a mutagen. The lack of mutagenicity corroborates the notion that the thyroid tumors are induced by a non-mutagenic mechanism. It appears that the rat thyroid is indirectly affected by the modulation of thyroxine clearance via increased hepatic metabolism. The alteration of thyroid hormone homeostasis in male rats appears to result in hypothyroidism. The chemical disruption mode of action of thiabendazole in animals, to the extent that it is applicable to humans, appears equally applicable to all human population subgroups. Children, therefore, are not expected to be more susceptible to thiabendazole-induced thyroid effects than adults.

In accordance with the Cancer Assessment Review Committee, the MOE approach was used to assess cancer dietary risk. Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) results in a Margin of Exposure (MOE) of 9,750 for the general US population.

Table 3. Estimated Acute, Chronic and Cancer Dietary Exposure/Risk.

Population Subgroup	Acute (Probabilistic) (99.9th %-ile)		Chronic		Cancer
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% cPAD	Margin of Exposure
U.S. Population	0.056656	57	0.001026	1	9,750
All infants (<1 yr)	0.057494	57	0.001623	2	NA
Children (1-6 yrs)	0.117065	117	0.002120	2	NA
Children (7-12 yrs)	0.068628	69	0.001376	1	NA
Females (13-50 yrs)	0.053284	53	0.000890	1	NA
Males (20+ yrs)	0.046693	47	0.000846	1	NA

Table 4. Acute Dietary Exposure/Risk Comparison.

Population Subgroup	Acute (Probabilistic) (99.9th %-ile)		Acute (truncating at tolerance) (Probabilistic) (99.9th %-ile)		Acute (using mushroom residues from chemigation only) (Probabilistic)		Acute (truncating at tolerance and using mushroom residues from chemigation only)	
	Exposure (mg/kg/day)	%aPAD	Exposure (mg/kg/day)	%aPAD	Exposure (mg/kg/day)	%aPAD	Exposure (mg/kg/day)	%aPAD
U.S. Population	0.056656	57	0.051728	52	0.037955	38	0.034286	34
All infants (<1 yr)	0.057494	57	0.056250	56	0.059941	60	0.056188	56
Children (1-6 yrs)	0.117065	117	0.100221	100	0.090203	90	0.076947	77
Children (7-12 yrs)	0.068628	69	0.057940	58	0.061917	62	0.045329	45

Females (13-50 years)	**0.053284**	**53**	**0.048900**	**49**	**0.024184**	**24**	**0.(**
Males (20+ yrs)	**0.046693**	**47**	**0.043199**	**43**	**0.023935**	**24**	**0.(**

4.3 Dietary Exposure (drinking water source)

The Environmental Fate and Effects Division (EFED; 1999 memo by Thuy Nguyen, D245780) has provided an analysis of available data and a screening-level assessment using simulation models to estimate the potential concentration of thiabendazole in ground and surface water. Thiabendazole is stable to photolysis on soil, has some mobility in sandy soil and is extremely persistent in the environment. The two major degradates comprise a relatively small fraction (<10%) of the total applied radioactivity in the laboratory studies; EFED believes that if present in the fields, their concentrations will not pose any major concern to the drinking water resource. The metabolites of thiabendazole were, therefore, not considered in the screening-level assessment.

Table 5. GENEEC and SCI-GROW EECs (ug/L) for thiabendazole use on wheat (seed treatment).

Model	EECs
Surface Water (GENEEC)	**Peak = 2.4 ppb (ug/L)** **Average 56 day = 0.52 ppb*(ug/L)**
Groundwater (SCI-GROW)	**0.01 ppb (ug/L)**

*** Value reported by EFED was 1.55 ppb, current HED policy states that the average 56 day GENEEC value should be divided by 3 for chronic DWLOC calculation**

4.3.1 Drinking Water Exposure

Since no thiabendazole water monitoring data were available, Environmental Fate and Effects Division (EFED) provided HED with modeling data on thiabendazole in surface water and groundwater. EFED model estimates used thiabendazole seed treatment on wheat seeds for calculation of Estimated Environmental Concentrations (EECs). EFED assumed a maximum application rate of 3.6 oz ai/100 lbs seed (0.2 lbs ai/A) and one application. GENEEC and SCI-GROW data are presented in Table 5 above.

GENEEC is not an ideal tool for drinking water exposure assessments. Surface-water-sourced drinking water tends to come from bodies of water that are substantially larger than a 1-hectare pond. Furthermore, GENEEC assumes that essentially the whole basin receives an application of the chemical. In virtually all cases, basins large enough to support a drinking water facility will contain a substantial fraction of area that does not receive the chemical. Furthermore, there is always at least some flow (in a river) or turn over (in a reservoir or lake) of the water so the persistence of the chemical near the drinking water facility is usually overestimated by GENEEC. Given all this, GENEEC does provide an upper-bound on the concentration of pesticide that could be found in drinking water and therefore can be appropriately used in screening calculations.

4.3.2 DWLOCs for Cancer Exposure

Cancer DWLOCs were not calculated since the MOE approach was used to estimate the cancer dietary (food) exposure. It should be noted, however, that the predicted 56-day average EEC from GENEEC will result in <1% of the exposure of food alone.

4.3.3 DWLOCs for Chronic Exposure

Chronic DWLOCs were calculated based on the chronic dietary (food) exposure and default body weights and water consumption figures. The EECs for surface water (GENEEC) were less than the chronic DWLOCs, indicating that chronic exposure to thiabendazole in food and water is less than HED=s level of concern. The EECs for groundwater (SCI-GROW) were less than the chronic DWLOC=s, indicating that chronic exposure to thiabendazole in food and water is less than HED=s level of concern. The Agency=s default body weights and water consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), 30 kg/1L (child) and 10 kg/1L (infant). To calculate the chronic DWLOC, the chronic dietary food exposure was subtracted from the chronic PAD as shown in the following equation:

where chronic water exposure (mg/kg/day) = [cPAD - (chronic food (mg/kg/day)]

$$\mathbf{DWLOC_{chronic}} = \frac{\mathbf{[chronic\ water\ exposure\ (mg/kg/day)\ x\ (body\ weight)]}}{\mathbf{[consumption\ (L)\ x\ 10^{-3}\ mg/\ g]}}$$

Table 6 Drinking Water Levels of Comparison for Chronic Dietary Exposure

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	$DWLOC_{chronic}$ (ug/L)	GENEEC (ug/L)	SCI-GROW (ug/L)
US Population	**0.1**	**0.0010**	**0.099**	**3500**	**0.5**	**0.01**

All infants < 1 yr	**0.1**	**0.0016**	**0.098**	**1000**	**0.5**	**0.01**
Children (1-6 yrs)	**0.1**	**0.0021**	**0.098**	**3000**	**0.5**	**0.01**
Children (7-12 yrs)	**0.1**	**0.0014**	**0.099**	**3000**	**0.5**	**0.01**
Females (13-50 yrs)	**0.1**	**0.0009**	**0.099**	**3000**	**0.5**	**0.01**
Males 20+	**0.1**	**0.0008**	**0.099**	**3500**	**0.5**	**0.01**

4.3.4 DWLOC for Acute Exposure

Acute DWLOCs were calculated based on the acute dietary exposure and default body weights and water consumption figures. The EECs for surface water (GENEEC) were less than the acute DWLOCs except for Children 1-6 years indicating that acute aggregate exposure to thiabendazole in food and water is less than HED's level of concern.

The EECs for groundwater (SCI-GROW) were less than the acute DWLOCs except for Children 1-6 yrs indicating that acute aggregate exposure to thiabendazole in food and water is less than HED's level of concern.

The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70 kg/2 L (adult male), 60 kg/2 L (adult female), 30 kg/1 L (child), and 10 kg/1 L (infant). To calculate the DWLOC, the acute dietary food exposure was subtracted from the acute PAD using the equation:

where acute water exposure (mg/kg/day) = [aPAD - (acute food (mg/kg/day)]

$$\mathbf{DWLOC_{acute}} = \frac{\mathbf{[acute\ water\ exposure\ (mg/kg/day) \times (body\ weight)]}}{\mathbf{[consumption\ (L) \times 10^{-3}\ mg/\ g]}}$$

Table 7. Drinking Water Levels of Comparison for Acute Dietary Exposure

Population	Acute PAD	Food Exposure	Max. Water Exposure (mg/kg/day)	$DWLOC_{acute}$ (ug/L)	GENEEC (ug/L)	SCI-GROW (ug/L)
US Population	**0.1**	**0.057**	**0.043**	**1500**	**2.4**	**0.01**
All infants	**0.1**	**0.057**	**0.043**	**430**	**2.4**	**0.01**

< 1 yr.						
Children 1-6 yrs.	**0.1**	**0.117**	**exceeds level of concern based on food alone**		**2.4**	**0.01**
Children 7-12 yrs.	**0.1**	**0.068**	**0.032**	**960**	**2.4**	**0.01**
Females 13-50 yrs.	**0.1**	**0.053**	**0.047**	**1400**	**2.4**	**0.01**
Males 20+	**0.1**	**0.047**	**0.053**	**1900**	**2.4**	**0.01**

4.4 Non-Dietary Exposure

Occupational thiabendazole exposure via dermal and inhalation routes can occur during handling, mixing, loading, and applying activities; in addition, the potential for postapplication occupational exposure is also likely. Furthermore, the potential for dermal contact with thiabendazole-treated commodities is likely when no protection to the hands, ie., gloves, are utilized in the post-dip sorting process. There is, also, a potential for residential exposure from paints and adhesives containing thiabendazole. Based on toxicological criteria and potential for exposure, HED has conducted dermal and inhalation exposure assessments for a variety of occupational and non-occupational scenarios.

4.4.1 Occupational Handler Exposure Scenarios

Current uses include post-harvest sprays, dips or drenches of citrus, apples, pears, mangoes, papayas, bananas, carrots and potatoes prior to shipping and storage. Thiabendazole may also be mixed with a wax formulation prior to application. Commercial seed treatment equipment is used for application to soybean and wheat seed. Although no data are available for occupational exposure when using commercial seed treatment, this is expected to be less than the exposure detected for manual (on-farm) seed treatment. The on-farm seed treatment exposure estimates are presented in the attached occupational and residential exposure assessment document (D. Jaquith, 9/00, D267084). Mushroom house treatments are multiple direct sprays. The current use pattern (based on REFs) suggests that occupational dermal and inhalation exposure durations are likely to be short- and intermediate- term for the post-harvest uses; chronic dermal and inhalation exposures may be likely for some industrial preservative uses. Residential handler dermal and inhalation exposures include use of latex or oil base paint formulations containing thiabendazole. Residential exposure may also include exposure to carpet, textile and paper treated with thiabendazole.

HED has identified 13 major exposure scenarios for which there is potential for occupational handler exposure during mixing, loading, and applying products containing thiabendazole to agricultural crops and to non-agricultural use sites (Table 8). These occupational scenarios

reflect a broad range of application equipment, application methods, and use sites. Post harvest application can be by dipping, spraying, or application during the waxing procedure for fruits and avocados. Also, post-application exposure can occur through secondary exposure, from thiabendazole that has been mixed with paints and adhesives or incorporated in the manufacture of textiles, paper and carpeting.

The estimated dermal and inhalation exposures (Table 9) considered baseline protection (long pants and a long-sleeved shirt, no gloves, and an open cab or tractor); however, additional personal protective equipment (PPE, which includes a double layer of clothing and gloves and/or a dust/mist respirator), and engineering controls (closed mixing/loading systems for liquids and granulars and enclosed cabs/trucks) can be used to mitigate exposure. Margins of exposure (MOE) reflecting baseline and PPE mitigation recommendations are presented in Table 10.

4.4.1.1 Occupational Handler Exposure Data Sources and Assumptions

An exposure assessment for each thiabendazole use scenario was developed using the Pesticide Handlers Exposure Database (PHED) Version 1.1 in conjunction with surrogate studies used in the exposure assessment for captan (seed potatoes) and chlorbenzilate (post-application sorting/ culling/ packing) and lindane (commercial seed treatment). PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases.

4.4.1.2 Occupational Handler Risk Characterization

The same endpoints were used for the assessment of dermal and inhalation risks; therefore, a risk assessment was conducted for combined short and intermediate dermal and inhalation exposures. MOEs for occupational handlers were derived based upon comparison of dermal and inhalation exposure estimates against a NOAEL of 10 mg/kg/day. NOAELs were based on reduced fetal body weight and histopathologic changes in liver, bone marrow and thyroid in rat subchronic and developmental oral toxicity studies. The absorbed fraction of each exposure was calculated in order to convert to an equivalent oral dose using a dermal absorption rate of 60% and 100% inhalation in conjunction with the relevant application rate. The estimated dermal absorption rate of 60% is based on results of an oral developmental toxicity study in rabbits (LOAEL=600 mg/kg/day) and a 21-day dermal toxicity study in rabbits (LOAEL > 1000 mg/kg/day). A ratio of the LOAELs from the oral and dermal studies indicated an approximate absorption rate of 60%. The uncertainty factors and target MOEs for

occupational workers are 100 for short-term dermal risk, intermediate-term dermal risk, and for short- and intermediate-term inhalation risk. MOEs below this level would represent a risk concern for the Agency.

A summary of the short-term and intermediate-term risk estimates for baseline, additional PPE, and engineering controls is presented in Table 10. Three short-term and intermediate-term scenarios require PPE to mitigate dermal risks from handling and/or applying thiabendazole-containing products. PPE is required to mitigate risk from dermal exposure during application in mushroom houses and post-harvest handling of treated commodities during sorting/culling/packing. The scenario for manual seed treatment was found to have an MOE which was above HED's level of concern; however no further recommendations for mitigation of exposure are being suggested since workers are already using PPE to minimize exposure. This scenario is also less prevalent than commercial seed treatment which in a surrogate study was found to yield relatively low levels of exposure (D. Jaquith, 9/00, D267084).

Dermal and Inhalation Risk Characterization: The estimates for short-term dermal and inhalation risks have been combined because dermal and inhalation risk assessments are based on the same toxicity endpoints.

Combined dermal and inhalation exposures reflecting baseline protective clothing result in MOEs that exceed HED's level of concern for only three scenarios, application to mushroom houses (11), post harvest exposure during sorting/ packing/culling (7), and manual seed treatment (4), where MOEs ranged from 32-77. **Provided that thiabendazole dermal exposures are mitigated for the above specified exposure scenarios with PPE and/or engineering controls, MOEs for dermal exposure/risk would not exceed HED's level of concern.** The contribution to risk via the respiratory route is negligible in all scenarios, especially due to applications which can potential contribute to prolonged exposures, ie., indoor uses such as paints, carpets and adhesives. **Inhalation exposure does not exceed HED's level of concern.**

4.4.2 Occupational Post-application Exposure

Because thiabendazole is applied as a post-harvest dip for citrus, pome fruits, mango, bananas, papaya, avocados and sugar beets, as well as, a preservative in paints and adhesives, OPP has concluded that there is a potential for occupational post-application exposure. Only one of four scenarios of post-application exposure resulted in an MOE that exceeded HED's level of concern. However, the exposure estimate derived in lieu of data is considered to be very conservative for the following reasons: (1) it was assumed that all of the thiabendazole on the treated surface could be transferred to the skin. The chemical is usually part of a wax matrix and quantitative transfer to the skin is unlikely; (2) the transfer coefficients for the hands were obtained from a field study in which contact with contaminated foliage was highly probable; a conveyor belt treatment line would be unlikely to have such a high degree of contact (probably

restricted to fingertips only). The MOE resulting from this scenario may be mitigated to a level of lesser concern by requiring additional PPE (double layer of clothing and chemical resistant gloves). **Provided that thiabendazole dermal exposures are mitigated for the above specified exposure scenario with PPE, MOEs for dermal/inhalation exposure/risk do not exceed HED's level of concern.**

HED has no data directly measuring the exposures of applicators using thiabendazole in mushroom houses. Thiabendazole is applied to mushroom houses during watering or by coarse spray. Of these, coarse spray application is considered to yield the higher potential for exposure and the exposure assessment is limited to this scenario. There are no data with which to address post application exposures but they would be expected to be less than those for a coarse spray applicator. In lieu of specific data it was necessary to use assumptions to estimate the surface areas of beds and tables, the areas that would be treated by coarse spray applicators.

Thiabendazole is occasionally applied as part of the manufacturing process for some paper products, canvas textiles, and incorporated into carpets. The Agency has no data addressing the potential exposures of individuals to these products. The fungicide is applied during the manufacturing process to non-food paper products, canvas textiles such as tents and awnings, and nylon carpet. Carpet would probably yield the highest contact. The material is applied via a trough during the manufacturing process to achieve a final level of 0.02-0.1% (paper), 0.05-0.3% (canvas), or 0.025-0.25% (nylon carpeting), based on finished product weight. The Agency has no data relating the weight of these products to the surface areas that could potentially lead to exposure. In lieu of such data an exposure estimate was derived from a study in the scientific literature measuring exposures of individuals performing activities on carpets following actuation of a total release fogger. It is recognized that the extrapolation from this study is highly uncertain and required several assumptions. A more complete description of the assumptions and calculations used in deriving the exposure values is presenting in the accompanying ORE chapter (D. Jaquith, 9/00, D267084).

4.4.3 Residential Handler Exposure

Due to thiabendazole's use profile, OPP has concluded that there is a low potential for residential exposure. The low concentrations of thiabendazole incorporated in paints, adhesives, paper and carpet greatly reduces the potential for exposure. Worst-case scenarios are described for both occupational and residential exposure to thiabendazole following incorporation into carpet (D. Jaquith, 9/00, D267084). The calculated dermal and inhalation exposure was found to be within the range of the target MOE value of 100: 100-1000 for adults, 59-590 for toddlers and 39-390 for infants (Table 10). Thiabendazole is usually used as a preservative in the backing of carpets and it is thought that these values may over-estimate actual exposure. In all cases residential exposure is not expected to exceed occupational post-application exposure and therefore would not be expected to exceed HED's level of

concern.

4.4.4 Cumulative Exposure

EPA does not have, at this time, available data to determine whether thiabendazole has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For risk assessment purposes, HED has not assumed that thiabendazole has a common mechanism of toxicity with any other chemicals.

4.5 Incident Reports

HED has reviewed the OPP Incident Data System (IDS), the Poison Control Center, the California Department of Food and Agriculture (Department of Pesticide Regulation), and the National Pesticide Telecommunications Network (NPTN) databases for reported incident information for thiabendazole. Two of three reports in the Incident Data System on thiabendazole involve eye irritation. The Poison Control Center data for 1993-96 (400,000+ exposures to pesticides) contains nine exposures to thiabendazole (six adults, two children under 6, and one 6-19 year old). Only two these exposures were reported to result in a minor medical outcome, 3 more were potentially minor or moderate but did not receive follow-up. Two had no symptoms and two had unrelated symptoms. Only two cases were seen in a health care facility and none was hospitalized. The California Department of Food and Agriculture data indicate that from 1982 through 1996, there were four cases of skin illness in packing/processing workers where thiabendazole was the primary pesticide responsible for the illness. One case required two days off work. None of the cases were hospitalized. These results suggest that thiabendazole has a very low potential for hazardous effects to humans. Based on these reports, exposure to thiabendazole can lead to skin and eye illnesses such as skin rashes and conjunctivitis that are short-lived.

Table 8. Exposure Scenario Descriptions for Uses of Thiabendazole (TBZ).

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader Exposure			
Mixing Liquid Formulations (6,11)	PHED V1.1	textbook/use report for mushrooms (see Appendix A)	**Baseline:** Hands, dermal, and inhalation = AB grades. Dermal = 72 to 122 replicates; hands = 53 replicates; inhalation = 85 replicates. High confidence in all data. No protection factor was needed to define the unit exposure. **PPE:** The same dermal data are used as for the baseline, and chemical resistant glove data are used for hands. Hand data are AB grades with 59 replicates. High confidence in hand data.
Applicator Exposure			
Applying paints with a paintbrush (8)	PHED V1.1	2 gallons of paint per day	**Baseline:** Hands, = B grades.; inhalation and dermal = C grade Dermal = 14 to15 replicates; hands = 15 replicates; inhalation = 15replicates. Low confidence for dermal; medium for inhalation. PHED data were used for baseline, no PFs were necessary.
Applying paints with an airless sprayer (9)	PHED V1.1	5 gallons of paint per day	**Baseline:** Hands, dermal, = B grades.; inhalation = C grade Dermal = 15 replicates; hands = 15 replicates; inhalation = 15replicates. High confidence for dermal; medium for inhalation. PHED data were used for baseline, no PFs were necessary.
Planting potato seed pieces (1)	Stevens et. al (see Appendix A); PHED V1.1	6 hours per day	Weak study from the scientific literature, not all body areas were represented; ratios of exposure inside and outside the clothing of mixer/loaders pouring wettable powders was used to address these deficiencies (see Appendix A). Previous reports used for work duration.
Observer on tractor planting potatoes (2)	Stevens et. al (see Appendix A); PHED V1.1	6 hours per day	Weak study from the scientific literature, not all body areas were represented; ratios of exposure inside and outside the clothing of mixer/loaders pouring wettable powders was used to address these deficiencies (see Appendix A). Previous reports used for work duration.
Manual seed treatment (4)	Fenske et al (see Appendix A.	8 hour per day. Data from study extrapolated to farm size.	Literature study used for estimate. Quality assurance data not available; 12 replicates conducted by 4 workers. Eight hours probably highly conservative.

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Commercial Seed Treatment (5)	No data	8 hours per day	Exposure was assumed to be less than manual seed treatment; the only available data source contained almost all non-detect samples.
Spray Application to Mushrooms (10)	PHED V1.1	10 houses per day	**Baseline:** Hands = BC grades; dermal = C grade; inhalation = ABC grades. Dermal = 13 replicates; hands = 9 replicates; inhalation = 13 replicates. Low confidence in all data. No protection factor was needed to define the unit exposure. **PPE:** The same dermal data are used as for the baseline, and chemical resistant glove data are used for hands. Hand data are BC grades with 4 replicates. Low confidence in hand data.
Post harvest treatment Exposures			
Mixer/loader for post harvest treatments (6).	PHED V1.1	2000 boxes per hour; 8 hours per day	**Baseline:** Hands, dermal, and inhalation = AB grades. Dermal = 72 to 122 replicates; hands = 53 replicates; inhalation = 85 replicates. High confidence in all data. No protection factor was needed to define the unit exposure.
Post treatment exposures during sorting/packing/culling (7)	Model developed	8 hour work day	Model developed from USDA data, Highest Average Field Trial (HAFT), and a study from the scientific literature. Apple is considered to represent a "standard" fruit. Considered highly conservative.
27 Post application from carpets, textilesn and paper (12a-c)	Ross, et al. (see Appendix A); Residential SOPs	8 hrs per day; 5 percent tansfer	Study does not match scenario; provides very conservative estimates

[a] Standard Assumptions based on an 8-hour work day as estimated by HED. BEAD use/usage data were not available.

[b] Data grades are defined by EPA SOP for meeting Subdivision U Guidelines, Series 875, Group A. Acceptable grades are matrices with grades A and B data.

Data confidence are assigned as follows:

High= grades A and B and 15 or more replicates ; Medium = grades A, B, and C and 15 or more replicates;

Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

Table 9 Dermal and Inhalation Exposure to Thiabendazole(TBZ)

Exposure Scenario (Scenario #)	Dermal Unit Exposure	Inhalation Unit Exposure[a]	Maximum Application Rate[b]	Daily Acres Treated[c]	Daily Dermal Exposure (mg/kg/day)[de]	Daily Inhalation Exposure (mg/kg/day)
Mixer/Loader Exposure/Cutter (for potato seed treatment)						
Filling duster for potato seed pieces, located outside facility (Rocky seed)(3a)	22 mg/hr[e]	1.7 mg/hr	0.005/100 lbs	30	0.075	0.0097
Filling duster for potato seed pieces, located outside facility (Clean seed)(3b)	12 mg/hr	0.61	0.005/100 lbs	30	0.041	0.0035
Filling duster for potato seed pieces, located inside facility (Clean seed)(3c)	2.0 mg/hr	0.15 mg/hr	0.005/100 lbs	30	0.0069	0.00086
Cutting Potato Seed Pieces, Complete Operation Inside (3d)	0.80 mg/hr	0.037 mg/hr	0.005/100 lbs	30	0.0027	0.00021
Cutting Potato Seed Pieces, Cutter Inside and Duster Outside (3e)	0.14 mg/hr	0.042 mg/hr	0.005/100 lbs	30	0.00048	0.00024

Exposure Scenario (Scenario #)	Dermal Unit Exposure	Inhalation Unit Exposure[a]	Maximum Application Rate[b]	Daily Acres Treated[c]	Daily Dermal Exposure (mg/kg/day)[de]	Daily Inhalation Exposure (mg/kg/day)
Mixing/loading for post harvest treatment of commodities (6)	2.9 mg/lb ai	0.0012 mg/lb ai	NA	NA	0.011	0.0000074
Mixing/loading for mushroom spraying (11)	2.9 mg/lb ai	0.0012 mg/lb ai	0.12 lb ai/500 ft^2	NA	0.030	0.000021
Applicator Exposure (Planter/Observer for Potato Seed Application)						
Applying paints containing TBZ to surfaces, paintbrush (8)	180	0.28	5 g/gal; 2 gal/day	NA	0.034	8.5×10^{-5}
Applying paints containing TBZ to surfaces, airless sprayer (9)	38	0.83	5 g/gal; 5 gal/day	NA	0.018	6.5×10^{-4}
Planting potato seed pieces (1)	0.71 mg/hr	0.037 mg/hr	0.005 lb/100 lbs	30	0.0024	0.00021
Observer on tractor planting potatoes (2)	0.63 mg/hr	0.027 mg/hr	0.005 lb/100 lbs	30	0.0026	0.000086
Manual seed treatment (4)	9.4 mg/lb ai	0.0016 mg/lb ai	0.005 lb/100lbs	NA	0.18	0.00005

Exposure Scenario (Scenario #)	Dermal Unit Exposure	Inhalation Unit Exposure[a]	Maximum Application Rate[b]	Daily Acres Treated[c]	Daily Dermal Exposure (mg/kg/day)[de]	Daily Inhalation Exposure (mg/kg/day)
Commercial seed treatment (5)	No data, not expected to exceed manual seed treatment	No data, not expected to exceed manual seed treatment	No data, not expected to exceed manual seed treatment	NA	No data, not expected to exceed manual seed treatment	No data, not expected to exceed manual seed treatment
Spraying mushrooms (10)	12	0.94	0.12 lb ai/500 ft^2	NA	0.12	0.016
Tree injection (13)	No data	No data	No data	NA	Not data, considered negligible	Not data, considered negligible
Post Harvest/Post Application Exposure						
Post harvest exposure during sorting/packing/culling (7)	NA	Negligible	NA	NA	0.31	Negligible
Post application exposure to treated carpet, textiles, or paper - Adult (12a)	NA	NA	NA	NA	0.01-0.10	Negligible
Post application exposure to treated carpet, textiles, or paper - Toddler (12b)	NA	NA	NA	NA	0.02-0.17	Negligible
Post application exposure to treated carpet, textiles, or paper - Infant (12c)	NA	NA	NA	NA	0.03-0.26	Negligible

a Inhalation exposure represents no respirator.

b Application rates were taken by examination of product labels.

c Daily acres treated values are from EPA HED estimates of acreage that could be treated or volume handled in a single day for each exposure scenario of concern.

d Daily Dermal Exposure (mg/kg/day) = Unit Exposure (mg/lb ai) * Appl. rate (lb ai/A) * Acres Treated ÷ 70 kg x dermal absorption factor of 0.6 OR

mg/hr x hrs/day x Appl rate of TBZ/Appl rate of surrogate ÷ 70 kg x dermal absorption factor of 0.6 OR see Appendix A for calculation of post harvest culling/sorting/packing operations.

e potato treatment exposure estimates were derived from a study in which 5 percent captan was used and assumes 6 hours of exposure (Stevens, et al., see Appendix A)

Table 10. Intermediate-term MOEs for Thiabendazole at Baseline and with Mitigation Measures

Exposure Scenario (Scenario #)	Baseline Daily Dose[a] (mg/kg/day)	Baseline MOEs[b]	Risk Mitigation Measures	
			Additional PPE[c]	
			Daily Dose[e] (mg/kg/day)	MOE[b]
Mixer/Loader Exposure and Dose Levels (includes Cutters for potato seed treatment)				
Filling duster for potato seed pieces, located outside facility (Rocky seed)(3a)	0.085	120	NA	NA
Filling duster for potato seed pieces, located outside facility (Clean seed)(3b)	0.045	222	NA	NA
Filling duster for potato seed pieces, located inside facility (Clean seed)(3c)	0.0078	1300	NA	NA
Cutting Potato Seed Pieces, Complete Operation Inside (3d)	0.0029	3400	NA	NA
Cutting Potato Seed Pieces, Cutter Inside and Duster Outside (3e)	0.00072	14000	NA	NA
Mixing/loading for post harvest treatment of commodities (6)	0.011	910	NA	NA
Mixing/loading for mushroom treatment (11)	0.030	333	0.0024	4200
Applicator Exposures and Dose Levels (includes Obseerver for Potato Treatment)				
Applying paints containing TBZ to surfaces, paintbrush (8)	0.034	290	NA	NA
Applying paints containing TBZ to surfaces, airless sprayer (9)	0.018	560	NA	NA
Planting potato seed pieces (1)	0.0026	3800	NA	NA

Exposure Scenario (Scenario #)	Baseline Daily Dose[a] (mg/kg/day)	Baseline MOEs[b]	Risk Mitigation Measures	
			Additional PPE[c]	
			Daily Dose[e] (mg/kg/day)	MOE[b]
Observer on tractor planting potatoes (2)	0.0023	430	NA	NA
Manual seed treatment (4)	0.18	56	NA	NA
Commercial seed treatment (5)	No data; not expected to exceed manual	No data; not expected to exceed manual	No data; not expected to exceed manual	No data; not expected to exceed manual
Application to mushroom houses (11)	0.13	77	0.089	112
Post Harvest and Post Application Exposures and Dose Levels				
Post harvest exposure during sorting/ packing/culling (7)	0.31	32	0.031	320
Post application exposure to treated carpet, textiles, or paper - Adult (12a)	0.01-0.1e	100-1000	NA	NA
Post application exposure to treated carpet, textiles, or paper - Children 1-6 (12b)	0.02-0.17	59-590	NA	NA
Post application exposure to treated carpet, textiles, or paper - Infant (12c)	0.03-0.26	39-390	NA	NA

a Baseline Daily Dose (mg/kg/day) = Baseline Daily Exposure (mg/day)/Body weight (70 kg).
Baseline exposures are reported in Table 2.

b Dermal MOE values calculated using the following equation: MOE = NOEL (mg/kg/day)/Dermal Dose (mg/kg/day), where dermal NOEL = 5.0 mg/kg/day and an MOE of 100 is required.

c Additional PPE consists of a single layer of clothing and gloves

d Daily Dermal Dose (mg/kg/day) = [(Unit Dermal Exposure (mg/lb ai) * Max. App. Rate (lb ai/A) * Max. Treated)/Body Weight (70 kg)]

e Derived from a literature study (Ross, et al., see Appendix A)

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

5.1 Acute Aggregate Risk

Estimated acute dietary exposure is above HED's level of concern for children 1-6 yrs. Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) in the assessment resulted in estimated dietary exposures (99.9^{th} percentile) corresponding to 57 % aPAD for the general US population and 117 % aPAD for children 1-6 years old, the most highly exposed population subgroup.

Using conservative screening-level models, the estimated maximum peak concentrations of thiabendazole in surface water is 2.4 ppb. This estimated peak concentration is less than HED's drinking water level of comparison for exposure to thiabendazole in drinking water as a contribution to aggregate acute dietary risk for all population subgroups except children 1-6, for which food alone exceeds the level of concern.

5.2 Short- and Intermediate-Term Aggregate Risks

Short- and intermediate term aggregate risk estimates are unlikely to exceed HED's level of concern. When considering upper-bound estimates, however, of non-occupational exposure (treated carpet), in addition, to dietary exposure, all population subgroups are found to exceed HED's level of concern (Table 11). However, since these estimates are based upon highly speculative assumptions (D. Jaquith, 9/00, D267084) which over-estimate exposure, using the lower-bound estimates of non-occupational exposure to carpet residues may be more accurate. The short- and intermediate-term aggregate risk including drinking water have been calculated using the reciprocal MOE equation to determine the DWLOC values for the U.S. population, infants, children, and male and female subgroups.

Two short- / intermediate-term residential exposures scenarios were identified for the adult populations: exposure to Thiabendazole-treated carpet and painting using Thiabendazole-treated paint. Since these scenarios can occur simultaneously, they were aggregated along with average dietary exposure in order to calculate the allowable contribution of thiabendazole residues from drinking water sources (see sample scenario below). For infants and children, only the carpet exposure was aggregated with average dietary exposure to calculate the allowable contribution of thiabendazole residues from drinking water sources. The estimated average concentrations of thiabendazole in surface and ground water are less than HED's levels of comparison for thiabendazole in drinking water as a contribution to short- and intermediate-term aggregate exposure. Therefore, taking into account the present uses, HED concludes with reasonable certainty that residues of thiabendazole in drinking water (when considered along with other sources of exposure for which HED has reliable data)

would not result in unacceptable levels of aggregate human health risk at this time.

Sample Scenario- Adult in a room with Thiabendazole-treated carpet using a paint brush to paint with Thiabendazole-treated paint.

$$MOE_{water} = \frac{1}{\frac{1}{MOE_{agg}} - \left[\frac{1}{MOE_{food}} + \frac{1}{MOE_{carpet}} + \frac{1}{MOE_{paint}}\right]} = \frac{1}{0.01 - [0.0001 + 0.001 + 0.0034]}$$

$$MOE_{water} = \frac{1}{0.0055} = 182 \qquad \text{Water exposure} = \frac{NOAEL}{MOE_{water}} = \frac{10}{182} = 0.055 \text{mg/kg/day}$$

$$DWLOC = \frac{0.055 \text{ mg/kg/day} \times 70 \text{ kg}}{2 \text{ L} \times 10^{-3} \text{ mg/g}} = 1900 \text{ µg/L}$$

Table 11. Aggregate Drinking Water Levels of Comparison for Short- and Intermediate Term Aggregate Exposure[a]

Population Subgroup	MOE_{agg}	MOE_{food}	$MOE_{exposure}$		MOE_{water}	$DWLOC_{agg}$ (µg/L)	GENEEC (µg/L)	SCI-GROW (µg/L)
			carpet	paint				
U.S. Population	100	10000	100-1000	290	190	1900	0.52	0.01
All infants < 1 yr.	100	6300	40-330	n/a	110	680	0.52	0.01
Children 1-6 yrs.	100	5000	60-500	n/a	120	2300	0.52	0.01
Children 7-12 yrs.	100	7700	100-1000	n/a	110	2700	0.52	0.01
Females 13-50 yrs.	100	11000	100-1000	290	180	1900	0.52	0.01
Males 20+	100	12000	100-1000	290	190	1900	0.52	0.01

[a] These calculations apply to chronic scenarios also. The calculations assume that carpet exposure is at the lowest end of the range (highest MOE).

5.3 Chronic Aggregate Risk

Chronic aggregate risk estimates do not exceed HED's level of concern. The aggregate chronic dietary risk estimates include exposure to thiabendazole residues in food and water. No chronic residential use scenarios were identified. Exposure from carpet may occur; however, this exposure should dissipate over time. The aggregate chronic risk would be equal to or less than (no contribution from paint residues) that calculated for short- and intermediate-term aggregate risk. Exposure (food only) to combined residues of thiabendazole and its metabolites of toxicological concern based on a Tier 3 refinement using average residues from field trial and percent of crop treated data, represents 2% of the cPAD for the most highly exposed population subgroup (children 1-6 years) and infants < 1year of age. Exposure to all other groups represents 1% of the cPAD. Using conservative screening-level models, the estimated average 56-day concentration of thiabendazole in surface water is 0.52 ppb. This estimated average concentration is less than HED's drinking water level of comparison for exposure to thiabendazole in drinking water as a contribution to aggregate chronic dietary risk. Based on the available information, HED concludes with reasonable certainty that no harm to any population will result from chronic aggregate exposure to thiabendazole.

5.4 Cancer Aggregate Risk

In accordance with the Cancer Assessment Review Committee, the MOE approach was used to assess cancer dietary risk. Use of PDP monitoring data, field trial data, and calculated livestock anticipated residues (ARs) results in a Margin of Exposure (MOE) of 9,750 for the general US population.

5.5 Conclusion

The estimated average concentrations of thiabendazole in surface and ground water are less than HED's levels of comparison for thiabendazole in drinking water as a contribution to short-term, intermediate-term, chronic and cancer aggregate exposure. Therefore, taking into account the present uses and uses proposed in this action, HED concludes with reasonable certainty that residues of thiabendazole in drinking water (when considered along with other sources of exposure for which HED has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

HED bases this determination on a comparison of estimated concentrations of thiabendazole in surface waters and ground waters to back-calculated "levels of comparison" for thiabendazole in drinking water. These levels of comparison in drinking water were determined after HED had considered all other non-occupational human exposures for which it has reliable data, including all current uses, and uses considered in this action. The estimates of thiabendazole in surface and ground waters are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and

ground water. Because HED considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, HED will reassess the potential impacts of thiabendazole on drinking water as a part of the aggregate risk assessment process.

6.0 DATA NEEDS

Additional data requirements have been identified in the attached Science Chapters and are summarized here.

Toxicology Data for OPPTS Guidelines:

In vitro mammalian gene mutation

In vitro chromosome aberration assay

It was concluded, however, that since there is confirming evidence that thiabendazole is aneugenic, no further genetic toxicity testing is required.

Occupational Exposure Data for OPPTS Guidelines

There are no exposure data for thiabendazole. The Agency was forced to use either surrogate data from the scientific literature, PHED and/or modeling techniques for the all of the exposure scenarios. The estimates of exposure should be considered to be highly conservative for these scenarios.

Product and Residue Chemistry Data for OPPTS Guidelines

Product Chemistry

All pertinent data requirements concerning the thiabendazole TGAI are satisfied for the EPA Reg No. 100-917 and EPA Reg. No. 100-963 technical products; however, a revised CSF is required. The registrant must certify that the suppliers of starting materials and the manufacturing processes for the thiabendazole and thiabendazole hypophosphite salt technicals and manufacturing-use products have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages.

Also the new data requirement concerning UV/visible absorption for the pure active ingredient (PAI) (OPPTS GLN 830.7050) remains outstanding.

Residue Chemistry

Additional data are required for multiresidue method testing for the thiabendazole metabolites benzimidazole and 5-hydroxy-thiabendazole. (OPPTS GLN 860.1360)

Additional storage stability data are required for sweet potatoes. (OPPTS GLN 860.1380)

Additional residue data are required for benzimidazole (free and conjugated) in/on cantaloupe and strawberry from foliar application of thiabendazole. All residues of concern should be measured in the required field trials. (OPPTS GLN 860.1500)

Residue data are required on thiabendazole and benzimidazole residues in/on each of the following grown from seed treated with thiabendazole: wheat, dry beans (if registrant intends to support due to numerous SLNs), and soybeans. No residue data are available for these use patterns. Alternatively, the uses must be canceled. (OPPTS GLN 860.1500)

A processing study is required for the processed fractions of soybeans. (OPPTS GLN 860.1520)

ATTACHMENTS (060101)

Report of the Hazard Identification Assessment Review Committee.
Report of the FQPA Safety Factor Committee.
Revised Product and Residue Chemistry Chapter.
Toxicology Chapter.
Revised Occupational and Residential Exposure Assessment.
Revised Dietary Exposure and Risk Estimates for Reregistration.
Environmental Fate and Effects Chapter.

cc Without Attachments: Caswell File